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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,104	09/27/2000	Alan P. Kozikowski	ZAA-012.01	6012

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EXAMINER

BHATTI, TAHIRA H

ART UNIT PAPER NUMBER

1627

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,104

Applicant(s)

KOZIKOWSKI ET AL.

Examiner

Tahira H Bhatti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-59 are pending in the present application and are subject to restriction and election of species requirements.
2. Please Note: In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Ph.D., Supervisory Patent Examiner at jyothsna.venkat@uspto.gov or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
3. *Restriction to one of the following inventions is required under 35 U.S.C. 121:*
 - aliphatic* Claims 1-10 and 27-36, drawn to a compositions of formula (1), classified in one of classes, 530 and 534-552 and numerous subclass depending on the structure of R1.
 - II. Claims 11-18, drawn to a method for treating disorders caused by a deficiency in monoamine concentration in a human by administering a pharmaceutically effective dose of a compound of formula (1) , classified in class, 424 and/or 514 and numerous subclass depending on the structure of R1.
 - III. Claims 23-26, drawn to a method comprising imaging the brain of a mammal by administering a radiolabeled compound comprising a

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radionuclide and a compound of formula (I), classified in classes, 424 and/or 514 and numerous subclass Depending on the structure of R1.

- IV. Claims 19-22 and 45-48, drawn to a compositions of radiolabel formula (I), classified in one of classes, 530 and 534-552 and numerous subclass depending on the structure of R1 and R2..
- V. Claims 37-44, drawn to a method for treating disorders caused by a deficiency in monoamine concentration in a human by administering a pharmaceutically effective dose of a compound of formula (II), classified in class, 424 and/or 514 and numerous subclass depending on the structures of R1 and R2.
- VI. Claims 49-52, drawn to a method comprising imaging the brain of a mammal by administering a radio labeled compound comprising a radio nuclide and a compound of formula (II), classified in class, 424 and/or 514 and numerous subclass, depending on the structure of R1 and R2.
- VII. Claims 53-54, drawn to a method inhibiting the reuptake of a monoamine Transporter comprising contacting a monoamine transporter with a compound having the formula (I), classified in class, 424 and/or 514 and numerous subclass, depending on the structure of R1.
- VIII. Claims 55-56, drawn to a method inhibiting the reuptake of a monoamine transporter comprising contacting a monoamine transporter with a compound having the formula (II), classified in class, 424 and/or 514 and numerous subclass, depending on the structure of R1 and R2.
- IX. Claims 57, drawn to a library of compounds having the formula (1), classified in class 435, and one of several digests, depending on the structure of R1.
- X. Claim 58, drawn to a library of compounds having the formula (II), classified in class 435, and one of several digests, depending on the structure of R1 and R2.
- XI. Claim 59, drawn to a method for detecting compounds capable of binding to monoamine transporters in inhibiting the uptake of

monoamines, classified in class 435, digest 2.

The inventions are distinct each from the other because:

4. Invention I and Invention (II, III and VII) are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of (product) of invention I can be used in the methods of invention II, III and VII.

5. Invention IV, and Inventions (V, VI and VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of (product) of invention II can be used in the methods of invention V, VI and VIII.

6. Inventions (I and IV) or (IX and X) are different and/or patentably distinct compositions. Each invention is different with regards to its chemical composition, chemical structures, and its physical and pharmacological properties and/or different

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reagents, starting materials, reaction conditions and method steps required for their making. The classification of each invention is different.

7. Inventions II, III, V-VIII and XI are directed to separate and distinct methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the method of treating disorders by administering formula I in group II is completely different from the methods of Group III which is directed to a method of imaging the brain of a mammal and administering radiolabeled formula I. Invention V is directed to a method for treating disorders by administering formula II and Invention VI is directed to a method of imaging the brain of a mammal and administering radiolabeled formula II. Invention VII is directed to a method of inhibiting the reuptake of a monoamine and a compound of formula I. Invention VIII is directed to a method of inhibiting the reuptake of a monoamine and a compound of formula II. Invention XI is directed to a method for detecting compounds capable of binding to a monoamine transporters. Each Invention is distinct and independent substantially in terms of different purpose. Different techniques are used for substantially different purposes.

8. Because these inventions are distinct for the reasons given above:

a. And have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification.

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b. Require different and independent burdensome manual/computer patent and non-patent literature searches, restriction for examination purpose as indicated is proper.

ELECTION OF SPECIES (FOR Groups I-XI)

9. This application contains claims directed to the following patentably distinct species of the claimed invention.

An election of species is required as set forth below.

If applicant elects

a. A single disclosed ultimate species of composition of formula (1) (i.e. precise chemical structure including ultimate species and connectivities for R1-R14, A and n) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

b. A single disclosed ultimate species of composition of formula (II) (i.e. precise chemical structure including ultimate species and connectivities for R1-R14), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made, See MPEP 812.02.

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15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to, Examiner Tahira Bhatti whose telephone number is (703) 605-1203. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsana Venkat (art unit 1627), can be reached at (703) 308 0570

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (702) 308-0196

Tahira Bhatti
(art unit 1627)
May 20, 2002


PADMAASHRI PONNALURI
PRIMARY EXAMINER
for SPE



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER: (703) 605-1203

TO EXAMINER: Tahina Bhatti

ART UNIT: 1627

SERIAL NUMBER: 09/671,104

FAX/TELECOPIER NUMBER: (703) 308-4315

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